DEPARTMENT OF H[illegible]LTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

Date: NOV 12 2003

04 JAN -[illegible]

From: Interdisciplinary Scientist/Pharmacist , Division of Dietary Supplement Programs , Office of Nutritional Products, Labeling and Dietary Supplements, HFS-810

Subject: 75-Day Premarket Notification of New Dietary Ingredients

To: Dockets Management Branch, HFA-305

Subject of the Notification: *Desmodium adscendens* D.C. (overground stems)

Firm: Biodynamics (Distributor)

Date Received by FDA: 1/31/03

90-Day Date: 5/01/03

In accordance with the requirements of section 413(a) of the Federal Food, Drug, and Cosmetic Act, the attached 75-day premarket notification and related correspondence for the aforementioned substance should be placed on public display in docket number 95S-0316 as soon possible since it is past the 90-day date. Thank you for your assistance.

Victoria Wetzel

for Gloria Chaney

P drive/ NDI/ NDI File Closeout/DDSP SOP closeout process...

95S-0316

RPT 170

DEPARTMENT OF H. LTH AND HUMAN SERVICES
Public Health Service

Food and Drug Administration
College Park, MD

APR 15 2003

Mr. Eric Maes
Biodynamics Nv
Joseph Plateaustraat 4
B-8400 Oostende
Belgium

Dear Mr. Maes:

This letter acknowledges receipt of a new dietary ingredient notification you sent to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 350(a)(2). On January 31, 2003, FDA received and filed your notification concerning a substance that you assert is a new dietary ingredient that was identified under the trade name "Desmodium." You describe the substance as the overground stems of *Desmodium adscendens* D.C in a liquid form under the trade name "Desmodium." On August 14, 2002, FDA sent a letter informing you that your original notification filed with FDA on May 31, 2002 did not comply with all the requirements of a new dietary notification specified in the Federal regulations at 21 CFR 190.6 and may be considered a drug under 21 U.S.C. 321(g)(1)(B). In response to the FDA letter of August 14, 2002, you sent this resubmission and indicated that this notification is to replace your original notification.

Your notification indicates that the overground stems of *Desmodium adscendens* D.C. are used to prepare a liquid form of the product in a concentration of 75 grams (g) of overground stems/150 mL of the liquid. Under conditions of use, you state that you want to market it as a support for liver function. You indicate that the target populations are adults and children and there are no other subgroups that should be excluded from the population of consumers. For serving levels you state "serving size: 2 doses of 10 mL/day for an adult and 3 ml/10 kg for a child."

In accordance with 21 U.S.C. 350b(a)(2), a manufacturer or distributor of a dietary supplement that contains a new dietary ingredient must submit certain information to FDA at least 75 days before the dietary ingredient is introduced or delivered for introduction into commerce. This information must include the basis on which the manufacturer or distributor has concluded that a dietary supplement containing such new dietary ingredient will reasonably be expected to be safe. FDA reviews this information to determine whether it provides an adequate basis for such a conclusion. Under section 350b(a)(2), there must be a history of use or other evidence of safety establishing that the dietary ingredient, when used under the conditions recommended or suggested in the labeling of the dietary supplement, will reasonably be expected to be safe. If this

requirement is not met, the new dietary ingredient may be deemed to be adulterated under 21 U.S.C. 342 (f)(1)(B), because there is inadequate information to provide reasonable assurance that the new dietary ingredient does not present a significant or unreasonable risk of illness and injury.

FDA has carefully considered the information in your notification and has concerns about the evidence on which you rely to support your conclusion that the ingredient, the overground stems of *Desmodium adscendens* D.C., will be reasonably expected to be safe for the suggested or intended uses.

Three non-clinical studies (two *in vitro*, one in *vivo*) were conducted to support the use of Desmodium adscendens. The *in vivo* , acute oral rat study was performed on a small number of animals and was based upon a single exposure test. The product has undergone no long term toxicologic study. No additional clinical or preclinical data are provided. It is unclear how the provided data are sufficient to support the safe use of the product.

In the three studies included in your notification, the test substances used appear to be dried plant material identified as *Desmodium adscendens*. The relationship between the dry plant material used in the studies and the liquid preparation that is the subject of the notification is unclear. The materials used in the studies appear to be 1% (weight/volume) or 2% preparations. In contrast, the product described in the notification appears to be a 50% (weight/volume) preparation (e.g., 75 g plant material/150 mL liquid).

In conclusion, the information in your notification does not appear to provide an adequate basis to conclude that the overground stems of *Desmodium adscendens* D.C., is reasonably expected to be safe when used under the recommended or suggested conditions of use. Therefore your product may be adulterated under 21 U.S.C. 342 (f)(1)(B) as a dietary supplement that contains a new dietary ingredient for which there is inadequate information to provide reasonable assurance that it does not present a significant or unreasonable risk of illness or injury. Introduction of such products into interstate commerce is prohibited under 21 U.S.C. 331 (a) and (v).

Your notifications will be kept confidential for 90 days after the filing date of January 31, 2003. After May 1, 2003, the notification will be placed on public display at FDA's Docket Management Branch in docket number 95S-0316. Prior to May 1, 2003, you may wish to identify in writing specifically what information in your notification you believe is proprietary for FDA's consideration.

If you have any questions concerning this matter, please contact Victoria Lutwak at (301) 436-2375.

Sincerely yours,

Susan Walker, M.D.
Acting Director,
Division of Dietary Supplement Programs
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

QUALITY HEALTH CARE PRODUCTS

[redacted] NV

RECEIVED
1/31/03
95S

Oostende, 16/01/03

Dear Sir, Madame,

ENTRY CODE: 112 0666 0285
Docket number: 95S-0316

In answer to your letter we received on 14 august 2002, about a notification of Desmodium adscendens:

- please ignore all the drug claims. We want to market our product as a food supplement, not as a drug. Our product will NOT be marketed with the intention to cure, mitigate, treat , or prevent several diseases as hepatitis, allergies, etc.
we want to market it as a support for the liver function.

- botanial description: family: fabacee , name: desmodium adscendens, initial of the botanist : D.C.

- we only want to market in the US, the product who's called " desmodium". Please discard the product called: "desmopar". This is an error from our behalf.

- subgroups: serving size : 2 dose of 10 ml/day for an adult and 3 ml / 10 kg for a child . there are no subgroups that should be excluded from the population of consumers.

- no toxicity: see enclosure (micronucleus test on the mouse, experiment of reverse mutation through the ames test, evaluation of the acute toxicity orally administered to the rat).

In the hope you're pleased with this information,

Yours sincerely,

Francis Maes,
C.E.O.

[redacted]
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